K112828

OCT 25 2011

SECTION 5. 510(k) Summary

(As Required By 21 CFR 807.92(a))

A. Submitter Information

Submitter's name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767
Telephone: 508-828-3312
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Contact Person: Catherine Kilshaw

Date of Submission: September 23, 2011

B. Trade/Device Name: REVIVE™ Intermediate Catheter
Common Name: REVIVE™ Intermediate Catheter
Classification Name: Percutaneous Catheter
Regulation Number: Class II per 21 CFR 870.1250

C. Predicate Devices:

Device	Company	510(k) Number/ Concurrence Date	Product Code	Predicate For:
ENVOY® Guiding Catheter	Codman & Shurtleff, Inc.	K982770	DQY	Intended Use Design Materials Sterilization
Courier ® Microcatheter	Codman & Shurtleff, Inc (Previously Micrus Endovascular,Corp)	K060116	DQY	Materials

D. Device Description:

The REVIVE™ Intermediate Catheter is a variable stiffness, single lumen catheter designed to aid the physician in access to vasculature and in the delivery and retrieval of devices. Multiple levels of stiffness ranging from a highly flexible tip to a semi-rigid proximal section along the length of the catheter are designed to aid the physician in tracking over guide wires. The Revive IC may also be delivered through the lumen of a larger bore guiding catheter. The catheter has an outer hydrophilic coating that reduces friction during manipulation in the vessel. The lubricious PTFE lined inner lumen is designed to facilitate movement of the guide wires and other devices. A luer fitting located on the end of the catheter hub can be used to attach accessories.

E. Intended Use:

The REVIVE™ Intermediate Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.

F. Summary of technological characteristics of the proposed to the predicate device:

The REVIVE Intermediate Catheter is substantially equivalent to the Codman ENVOY Guiding Catheter and the Courier Microcatheter. No new technological characteristics are being introduced with the proposed device.

The REVIVE IC has the same intended use as the ENVOY Guiding Catheter and it is similar with regard to design, materials, manufacturing and sterilization process. Both the REVIVE IC and the ENVOY feature a nylon body which is reinforced with stainless steel. REVIVE's multiple levels of stiffness from the highly flexible tip to a semi-rigid proximal section along the length of the catheter are designed to aid the physician in tracking over guide wires. This is similar to ENVOY which has three transition segments comprised of various durometers, along with a radiopaque filler. Both devices contain a soft, atraumatic distal tip.

In addition, the REVIVE IC is similar to the Courier Microcatheter with regard to materials. The base materials of the four major components of the REVIVE IC (hub & shaft, PTFE liner, stainless steel reinforcement, hydrophilic coating) are identical to the Courier.

All three devices are PTFE lined, have either a metallic braid or coil reinforcement, a polymer jacket of decreasing durometer from proximal to distal end, and a radiopaque marker at the distal tip. They are all EtO sterilized, packaged in a tyvek pouch and mounted either in a mounting card or plastic hoop.

G. Testing Summary:

Preclinical testing data to demonstrate that the device performs according to its description and intended use were used to establish the performance characteristics

of the modifications to this device. Clinical testing was not required to establish substantial equivalence.

Results of verification and validation conducted on the REVIVE IC demonstrate that it performs as designed, is suitable for its intended use, is substantially equivalent to the predicate device and therefore, does not raise any new issues of safety and effectiveness. The following tests were conducted:

- Shaft Kink Resistance
- Kink Resistance at Proximal End
- Catheter Lumen Patency
- Ability to Track to Target Sites
- Fluoroscopic Verification
- Trackability
- Catheter Length Verification
- Catheter Diameter Verification
- Compatibility with Guiding Catheters
- Compatibility with Microcatheters
- Luer Tapering
- Hub Transitioning
- Hub Attachment Tensile Strength
- Shaft Tensile Strength
- System Liquid Air Leakage
- System Air Leakage
- Tip Atraumaticity
- Coating Integrity
- Burst Test
- Flow Rate Test

The REVIVE IC met all the biocompatibility requirements as specified by the ISO 10993 Part I, and the General Program Memorandum # G95-1 on Biological Evaluation of Medical Devices. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility

- Thrombogenicity
- Genotoxicity

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Codman & Shurtleff, Inc., it is concluded that the REVIVE Intermediate Catheter is substantially equivalent to the ENVOY Guiding Catheter and the Courier Microcatheter and therefore, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Codman & Shurtleff, Inc.
c/o Ms. Catherine Kilshaw
Regulatory Affairs Specialist II
325 Paramount Dr.
Raynham, MA 02767-0350

OCT 2 5 2011

Re: K112828
Trade/Device Name: REVIVE™ Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 26, 2011
Received: September 28, 2011

Dear Ms. Kilshaw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112828

Device Name: REVIVE™ Intermediate Catheter

Indications For Use:

The REVIVE™ Intermediate Catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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